Non-Technical Abstract

CLL is an indolent B-cell leukemia/lymphoma incurable with current available chemotherapy agents. It is well established that the dominant CLL cell clone expresses a tumor-specific DNA sequence. With current molecular techniques, the patient's own tumor-specific DNA sequence can be copied and cloned in a bacterial plasmid to produce a patient-specific DNA vaccine. Furthermore, this process of producing enough vaccine for patient use, normally very time-consuming, can be generated by the bacterial vector very quickly. This is the rationale to using plasmid technology: to prepare vaccines quickly and unique to each patient's biology. Preliminary use of this technology in other indolent lymphomas has proven that this approach is safe and capable of triggering immune responses.

In the present study, our plan is to evaluate the immune and clinical responses of patients with early stage chronic lymphocytic leukemia (CLL) vaccinated with a DNA plasmid vaccine containing the patient's own specific gene sequence. The main objectives of this trial are: 1) to determine if patients with Binet Stage A CLL generate an immune response to a DNA vaccine; 2) to determine the optimal dose of the DNA vaccine to obtain an immune response in patients with early stage CLL; 3) to characterize any adverse effects of vaccination with a DNA vaccine; and 4) to determine if the DNA vaccine is capable of inducing remission in patients with early stage CLL.